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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,571	03/03/2004	Neil T Dear	ABB10010P0630US	9704

32116 7590 01/12/2007  
WOOD, PHILLIPS, KATZ, CLARK & MORTIMER  
500 W. MADISON STREET  
SUITE 3800  
CHICAGO, IL 60661

EXAMINER
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SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
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1652

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/12/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/009,571

Applicant(s)

DEAR ET AL.

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1652.

Applicant's response of November 13, to the First Action on the Merits mailed August 8, 2006, is acknowledged. It is acknowledged that Claims 1-5 have been amended. Claims 1-6 are pending. Claim 6 was previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions. Claims 1-5 are hereby reexamined.

#### ***Drawings***

Objection to Figure 1 for disclosing sequences that are not identified by a sequence identifier number (SEQ ID NO: ) is maintained; corrections have not been made.

#### ***Specification-Objections***

Objection to the specification for improper formatting is maintained; corrections have not been made.

Objection to the specification for containing hyperlinks is maintained; corrections have not been made.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

*Utility*

Rejection of Claims 1-5 under 35 U.S.C. 101/112 because the claimed invention lacks patentable utility is maintained. In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

(A) The application leaves no doubt that the CAPN11 sequence is expressed most strongly in testis (Fig 3).

(B) It is also established that CAPN11 is involved in processes like germ cell apoptosis or regulation of testis-specific transcription factors (pg 3).

(C) CAPN11 can be used as a bait for identifying inhibitors, which can be used for treatment of disorders associated with elevated CAPN11 activity, such as infertility in men (pg 4).

(D) The wrong conclusion has been drawn regarding Ben-Aharon et al, 2006. The abstract clarified that the expression and localization of calpain-11 suggest that it is involved in regulating calcium-dependent events during meiosis and sperm functional processes. Thus, CAPN11 is clearly involved in spermatogenesis and tinkering therewith is useful in treating diseases associated with an increase CAPN11 activity or infertility in men.

These arguments are not found to be persuasive for the following reasons.

(A) Reply: It is acknowledged that, of the tissues tested, RNA levels encoding the protein of SEQ ID NO: 2 are most highly expressed in testis. However, said RNA is not specific for testis, since it is also expressed in other tissues, including mammary gland and thymus (Fig 3; D8).

(B) Reply: It is acknowledged that the specification states that "In the testis, it [CAPN11] might be involved in processes in which calpains in other tissues are involved, such as germ cell apoptosis or the regulation of testis-specific transcription factors". Such a statement of

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what CAPN11 might be involved in is not a disclosure of what cellular or biochemical processes or diseases CAPN11 is involved in and does not provide a specific and substantial utility.

(C) Reply: The protein of SEQ ID NO: 2 cannot be used for identifying inhibitors because an assay for measuring activity has not been provided i.e., substrates and assay conditions to be used; see the rejection of Claims 4 and 5 under 35 USC 112, first paragraph/written description. Moreover, even if the specification provided an inhibitor assay using an artificial substrate, which it does not, the specification fails to teach the skilled artisan how to use any inhibitor of CAPN11 activity. The specification fails to teach any specific diseases or disorders to be treated or diagnosed or any specific cellular or biochemical processes to be analyzed. Mere assertion that inhibitors of CAPN11 activity can be used to treat infertility does not provide a patentable utility for the protein of SEQ ID NO: 2.

(D) Reply: It is acknowledged that the last sentence of the abstract for Ben-Aharon et al states that "The expression of calpain 11 during spermatogenesis and its localization in spermatozoa suggest that it is involved in regulating calcium-dependent signal transduction events during meiosis and sperm functional processes." However, said statement that the expression and localization of calpain 11 suggests that calpain 11 is "involved" in the general process of meiosis or any function of the sperm is not a disclosure of a specific and substantial function for CAPN11. Moreover, the purpose of citing Ben-Aharon et al in the prior action is to point out that as recently as 2006 the substrates and function of calpain-11 were yet to be determined (Ben-Aharon et al, 2006; pg 772, parg 4).

For these reasons and those explained in the prior action, rejection of Claims 1-5 under 35 U.S.C. 101/112 because the claimed invention lacks a substantial and specific utility is maintained.

#### **Written Description**

Rejection of Claims 4 and 5 under 35 U.S.C. 112, first paragraph/written description, as described in the prior action, is maintained.

In support of their request that said rejection be withdrawn, Applicants argue that the specification, at page 4, clearly discloses that CAPN11 is a calcium-dependent protease. Said page of the specification merely asserts that the protein of SEQ ID NO: 2 has homology to chicken  $\mu$ /m calpain, which is not a disclosure of a method for identifying inhibitor for the protein of SEQ ID NO: 2, as recited in Claims 4 and 5.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

#### **Final Comments**

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

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It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.  
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**SHERIDAN SWOPE, PH.D.**  
**PRIMARY EXAMINER**